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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,397	08/16/2001	Clayton Ericson	T8273	3898

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 03/31/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,397

Applicant(s)

ERICSON ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-20 and 22-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-20, and 22-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-3, 5-9, 11-20, and 22-28 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 98/48648. The WO Patent Application '648 teaches compositions comprising Ferrocel, which is an iron glycine chelate having a glycine:iron molar ratio of 2:1; an organic acid such as citric acid, malic acid, lactic acid, acetic acid, and Vitamin C (i.e. ascorbic acid); and a sugar such as sucrose. The organic acids prevent the iron source from generating undesired off-colors. The compositions can be prepared by dry blending followed by hydration, but also can be formed by spray drying. See, e.g., page 12, lines 1-34; page 13, lines 26-36; page 15, line 7-11; Examples 3, 5-12; and claims 20-29. The WO Patent Application '648 does not teach Applicants' claimed solubilizing agent:iron content weight ratios and sugar content:iron content weight ratios, and does not teach the order of combining components specified in instant claims 14-16. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal weight ratios of the components present in the compositions of the WO Patent Application '648 because component ratio is an art-recognized result-effective variable which is routinely determined and optimized in the beverage and food arts. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to alter the order of combining components in the method of the WO Patent Application '648 because the WO Patent Application '648 teaches that a variety of means can be used to prepare the compositions, because selection of any order of mixing ingredients is prima facie obvious (see MPEP 2144.04(IV)(C)), and because the same composition appears to form regardless of the order chosen.

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3. Claims 1, 3, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Pederson et al (U.S. Patent No. 5,516,925). Pederson et al teach forming iron(III)lysyl glycerophosphate in an aqueous solution, and then adding malic acid. The weight ratio of malic acid:iron is about 2.4:1. See, e.g., column 11, Example 8.

4. Claims 3, 7, 8, 10, 14 and 16 are rejected under 35 U.S.C. 103(a) as being obvious over Pederson et al (U.S. Patent No. 5,516,925). Application of Pederson et al is the same as in the above rejection of claims 1, 3, and 9. More generally, Pederson et al disclose preferred organic acids which are citric acid, succinic acid, and lactic acid (see, e.g., column 6, lines 20-22), but do not teach the combination of these acids with an iron amino acid chelate. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to form the iron amino acid chelates of Pederson et al using citric acid, succinic acid, or lactic acid because Pederson et al disclose these acids to be useful in improving the palatability of amino acid chelates, and because the substitution of one known functional equivalent for another is prima facie obvious. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal component ratios for the organic acids and the iron of Pederson et al because component ratio is an art-recognized result-effective variable which is routinely determined and optimized in the beverage and food arts. Pederson et al disclose adding malic acid to the solution of iron(III) lysyl glycerophosphate, but do not teach whether the malic acid is in dry or aqueous form. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to add the malic acid of Pederson et al in either dry or aqueous form, because this reflects merely an alteration in the

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order of combining components which is prima facie obvious (see MPEP 2144.04(IV)(C)), and because the same composition appears to form regardless of the order chosen.

5. Applicant's arguments filed February 19, 2003 have been fully considered but they are not persuasive.

The obviousness rejection based upon the WO Patent Application 98/48648 is maintained. Applicants argue that the embodiments of the reference should be looked at in order to understand what the reference "actually teaches and enables". Firstly, all of the disclosure of the reference, and not just the reference's embodiments or examples, must be evaluated for what the reference fairly teaches those of ordinary skill in the art. The disclosure of a reference is not limited to the references embodiments or examples. See MPEP 2123 and *In re Snow*, 176 USPQ 328 (CCPA 1973). Secondly, all the disclosure of a reference is presumed operable and enabled, and the burden lies upon Applicants to provide facts rebutting this presumption. See MPEP 2121. Applicants have not provided any such facts. Thirdly, the examiner recognizes that there is conflict in the WO Patent Application '648's disclosure of its organic acid:iron ratios. In particular, at page 12, lines 29-33, the disclosed ratios require equal or greater amounts of organic acid, whereas at claims 24-27, the recited ratios require equal or greater amounts of iron. However, regardless of which disclosure is correct, there is overlap between the disclosed or the claimed ratios of the WO Patent Application '648 and Applicants' claimed ratios, which embrace about equal amounts of organic acid and iron. Any overlap in range between a prior art reference and Applicants' claims is sufficient to establish prima facie obvious. See MPEP 2144.05(I); *In re Malagari*, 182 USPQ 549, 553 (CCPA 1974); and *In re Peterson*, 65 USPQ2d

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1379, 1382 (CAFC 2003). Applicants have not submitted any evidence to rebut this prima facie case of obviousness.

The rejections based upon Pederson et al are maintained. Applicants contend that in Pederson et al, the organic acid, e.g., the malic acid of Example 8, reacts with the iron amino acid chelate whereas Applicants' claims exclude such reaction. The examiner does not agree that Pederson et al react malic acid with the iron amino acid chelate in Example 8. Note that Example 8 uses the term "reacting" (see column 11, line 9) in conjunction with the ferrous sulfate, lysine, and calcium glycerophosphate and not in conjunction with the malic acid. With respect to the malic acid, Pederson et al use the verb "added" (see column 11, line 12), which is consistent with Applicants' "admixing" step. Further, because the same organic acid is being added to the same iron amino acid chelate in Example 8 of Pederson et al as in Applicants' claimed method, and because no special conditions are mentioned in Pederson et al's Example 8 for the addition step, a reaction between the organic acid and the iron amino acid chelate will not occur in Pederson et al any more than such a reaction will occur in Applicants' claimed method. Finally, the examiner agrees that some type of interaction or complex will occur between the malic acid and the iron amino acid chelate of Pederson et al, hence the terminology "iron(III) lysyl glycerophosphate/malate" in Example 8. However, some type of interaction or complex will necessarily occur between Applicants' organic acid and iron amino acid chelate, or else the organic acid will not be able to affect the solubility of the iron amino acid chelate as intended by Applicants. There is no evidence that any reaction occurs in Pederson et al which does not also occur in Applicants' claimed method, and accordingly Pederson et al is not distinguished on this basis.

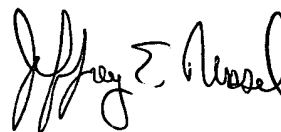
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6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
March 27, 2003